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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 16313-0238		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/26593	International filing date (day/month/year) 25 August 2003 (25.08.2003)	Priority date (day/month/year) 23 August 2002 (23.08.2002)	
International Patent Classification (IPC) or national classification and IPC IPC(7): A01H 1/02; C12N 15/31, 15/55, 15/82 and US Cl.: 800/274, 278, 287, 288, 300, 303, 306; 435/199, 320.1, 462			
Applicant BASF PLANT SCIENCE GMBH			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

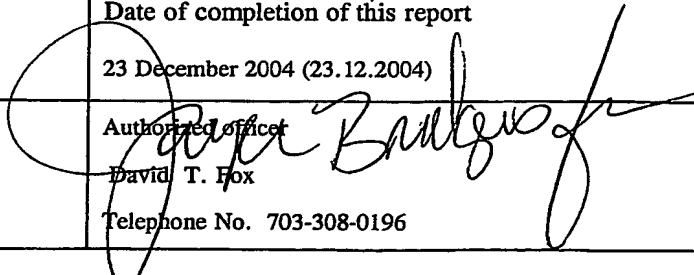
2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 23 March 2004 (23.03.2004)	Date of completion of this report 23 December 2004 (23.12.2004)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer  David T. Fox Telephone No. 703-308-0196

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/26593

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-52 _____ as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☒ the claims:
pages 53 and 54 _____, as originally filed
pages NONE _____, as amended (together with any statement) under Article 19
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☐ the drawings:
pages NONE _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☒ the sequence listing part of the description:
pages 1-4 _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in printed form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>1-11 and 14</u>	YES
	Claims <u>12-13</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-14</u>	NO
Industrial Applicability (IA)	Claims <u>1-14</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Please See Continuation Sheet

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

V. 2. Citations and Explanations:

Claims 1-14 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Claims 12-13 lack novelty under PCT Article 33(2) as being anticipated by HODGES et al (US 5,929,307).

HODGES et al teach a vector comprising a FLP recombinase gene and a nucleotide sequence of interest encoding a suicide protein, flanked by lox recombinase recognition sites (see, e.g., Figures 1a-1d and 3).

Claim 14 lacks an inventive step under PCT Article 33(3) as being obvious over HODGES et al (US 5,929,307) in view of BEDBROOK et al (US 5,013,659).

HODGES et al teach a vector comprising a recombinase gene, a nucleotide sequence of interest, and recombinase recognition sites, as discussed above, but do not teach the presence of an altered ALS nucleic acid that confers herbicide tolerance.

BEDBROOK et al teach an altered ALS nucleic acid and Brassica transformation therewith, for the purpose of conferring herbicide resistance (see, e.g., column 4, line 62 through column 5, line 20; column 57, line 65 through column 60, line 16).

It would have been obvious to one of ordinary skill in the art to utilize the vector taught by HODGES et al, and to modify that vector by incorporating the altered ALS gene conferring herbicide resistance taught by BEDBROOK et al as the nucleotide sequence of interest, given the teaching of BEDBROOK et al of the advantages of plant transformation with this gene.

Claims 1, 4-8 and 11-13 lack an inventive step under PCT Article 33(3) as being obvious over HODGES et al (US 5,929,307) in view of ODELL et al (US 5,658,772).

HODGES et al teach a vector comprising a FLP recombinase gene, further comprising a suicide gene encoding barnase as a nucleotide sequence of interest, said suicide gene operably linked to a male tissue-specific (tapetum-specific) promoter, said genes flanked by recombinase recognition sites; and plant transformation therewith for the production of male sterile plants which may revert to male fertility upon recombinase-mediated excision of the suicide gene construct (see, e.g., Figures 1a-1d and 3; column 2, line 65 through column 3, line 15; claims 1-13).

HODGES et al do not teach a method for transformant selection comprising the use of recombinase genes, recombinase recognition sites, and male sterility or fertility restoration.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

ODELL et al teach the advantages of the recombinase system for the excision of unwanted marker or trait genes, and also teach the use of the recombinase system with male sterility gene constructs (see, e.g., column 4, lines 16-28; column 10, lines 1-9; column 40, lines 1-40).

It would have been obvious to one of ordinary skill in the art to utilize the vector comprising a male sterility gene, recombinase gene, and recombinase recognition sites for the production of male sterile and male fertile plants as taught by HODGES et al, and to modify that method by utilizing the vector as a tool for identifying transformed plant cells and plants, as suggested by ODELL et al.

Claims 2-3 and 9-10 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of BEDBROOK et al (US 5,013,659).

The immediately preceding prior art teach a method of selecting transformed plant cells via a recombinase system and a male sterility system as discussed above, but do not teach Brassica transformation. ODELL et al also teach the use of an altered ALS gene in such a system (see, e.g., column 9, lines 26-40).

BEDBROOK et al teach Brassica transformation with a gene construct encoding an altered ALS protein for conferring an agronomic trait or for use as a transformation marker (see, e.g., column 4, line 62 through column 5, line 20; column 57, line 65 through column 60, line 16).

It would have been obvious to one of ordinary skill in the art to utilize the recombinase-mediated method of plant transformation taught by the previously cited combination of references, and to modify that method by incorporating the Brassica transformation method taught by BEDBROOK et al, given the common use of the altered ALS gene in both systems, and the recognition by those of ordinary skill in the art of the advantages of transforming a wide variety of agronomically useful crops, and the advantages of excising a wide variety of selectable markers to avoid environmental contamination thereof.